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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/552,327 | 10/07/2005 | Ee Chee Ren | 22516-US | 8907 |

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| EXAMINER | |
|---|---|
| HORLICK, KENNETH R | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/552,327 | REN ET AL. | |
| | Examiner | Art Unit | |
| | Kenneth R. Horlick | 1637 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *16 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 October 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Applicant's election without traverse of SEQ ID NO:11, 12, 15, 16, 18, 19, 20, 22, 27, and 28 in the reply filed on 05/16/08 is acknowledged.

2. The remaining SEQ ID NOs are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 05/16/08.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed (oligonucleotide-based detection).

5. Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and **should include that which is new in the art to which the invention pertains**. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract

**should include the technical disclosure of the improvement**. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:
(1) if a machine or apparatus, its organization and operation;
(2) if an article, its method of making;
**(3) if a chemical compound, its identity and use**;
(4) if a mixture, its ingredients;
**(5) if a process, the steps**.

Extensive mechanical and design details of apparatus should not be given.

6. The specification is objected to because of the following informality: the Brief Description of the Drawings (BDOD) and the drawings filed 10/07/05 are not in agreement. While six figures are described in the BDOD, only four figures were filed. Also, the current descriptions do not match the content of the drawings. Correction is required.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) These claims are confusing because it is unclear what is meant by "complement(s)", as this might allow for mismatches. It is suggested that the claims be amended to recite "full complement(s)".

B) Claim 3 is confusing because it is unclear how an oligonucleotide may "comprise a probe nucleic acid or a primer nucleic acid". The terms "probe" and "primer" refer to an intended use of an oligonucleotide, rather than to a structural feature of an oligonucleotide. Clarification is required.

C) Claim 32 is confusing because it cannot be determined what "character strings", "sequences", and "nucleic acids" "correspond to" a plurality of sequences, one or more recited SEQ ID NOs, and one or more character strings, respectively. In other words, the use of "correspond to" in this context renders the claims indefinite. Clarification is required.

8. Upon reviewing the priority applications, it has been determined that priority with respect to the examined SEQ ID NOs is as follows:

| | | |
|---|---|---|
| SEQ ID NO:11, 12, 27 | 04/21/03 | (provisional '115) |
| SEQ ID NO:15, 16 | 04/22/03 | (provisional '345) |
| SEQ ID NO:18, 19, 20, 28 | 04/24/03 | (provisional '965) |
| SEQ ID NO:22 | 08/19/03 | (provisional '016) |

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by Database accession no. AY269391, published 16 April 2003.

This reference teaches a 405-nucleotide nucleic acid which contains the sequences of instant SEQ ID NO:15 at nucleotide positions 148-168, instant SEQ ID NO:16 at nucleotide positions 227-247 (complement), and instant SEQ ID NO:20 at nucleotide positions 136-159 (complement). This sequence cannot be distinguished from the claimed oligonucleotide.

11. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Peiris et al. (US 7,267,942)(priority to prov. 60/462,805 14 April 2003).

In Fig. 9, Peiris et al. disclose Sequence 13, a 729-nucleotide nucleic acid which contains the sequence of instant SEQ ID NO:12 at nucleotide positions 395-418 (complement), instant SEQ ID NO:15 at nucleotide positions 148-168, instant SEQ ID

NO:16 at nucleotide positions 227-247 (complement), instant SEQ ID NO:18 at nucleotide positions 33-56, instant SEQ ID NO:19 at nucleotide positions 20-45 (complement), and instant SEQ ID NO:20 at nucleotide positions 136-159 (complement). This sequence of Peiris et al. cannot be distinguished from the claimed oligonucleotide.

12. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Maes et al. (US 7,255,986)(priority to prov. 60/353,608 31 Jan. 2002).

In Fig. 4, Maes et al. disclose Sequence 12, a 251-nucleotide nucleic acid which contains the sequence of instant SEQ ID NO:11 at nucleotide positions 229-251. This sequence of Maes et al. cannot be distinguished from the claimed oligonucleotide.

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2-12 and 28-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over any one of Database accession no. AY269391, Peiris et al., or Maes et al., in view of Buck et al.

These claims are drawn to an oligonucleotide as described and rejected above, wherein the oligonucleotide has 100 or fewer nucleotides, as well as to a composition, kit, and system comprising such an oligonucleotide.

The primary references each teach an oligonucleotide which is greater than 100 nucleotides in length.

Buck et al. teach that in general, given a known nucleic acid sequence, oligonucleotide fragments useful as probes and primers may be generated along the entire length of said known sequence, with reasonable expectation of success (see entire reference on pages 528-536, especially page 535).

One of ordinary skill in the art would have been motivated to make oligonucleotides of 100 or less nucleotides based on the sequences of any one of the primary references, including those comprising or consisting of the recited SEQ ID NOs, because as supported by Buck et al. such oligonucleotides would have been expected to be useful as probes and primers for detection of the corresponding target sequence. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to make and use the claimed oligonucleotides. It is noted that the further limitations of the dependent claims, such as modified nucleotides and labels, clearly relate to conventional and well known primer/probe technology and thus do not bear on

patentability. The same is true for the further limitations of independent claims 28, 29, 31, and 32, such as a sample, kit container, detector, computer, and synthesizer.

14. Claims 13-15, 17-22, and 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over either of Database accession no. AY269391 or Peiris et al., in view of Buck et al.

These claims are drawn to methods of using an oligonucleotide as described and rejected above to detect a severe acute respiratory syndrome coronavirus (SARS) in a sample.

The primary references each teach a SARS coronavirus oligonucleotide which is greater than 100 nucleotides in length, and comprises the recited SEQ ID NOs.

Buck et al. teach that in general, given a known nucleic acid sequence, oligonucleotide fragments useful as probes and primers may be generated along the entire length of said known sequence, with reasonable expectation of success (see entire reference on pages 528-536, especially page 535).

One of ordinary skill in the art would have been motivated to make and use oligonucleotides of 100 or less nucleotides based on the SARS coronavirus sequences of one of the primary references, including those comprising or consisting of the recited SEQ ID NOs, because as supported by Buck et al. such oligonucleotides would have been expected to be useful as probes and primers for detection of the corresponding SARS coronavirus target sequence in a sample. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to make and use the

claimed oligonucleotides in the claimed methods. It is noted that the further limitations of the dependent claims clearly relate to conventional and well known primer/probe technology (hybridization and amplification assays) and thus do not bear on patentability.

15. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Peiris et al. in view of Buck et al.

This claim is drawn to a method as described and rejected above, wherein the oligonucleotide comprises SEQ ID NO:27.

The sequence taught by Peiris et al., further to what has already been pointed to above, also comprises instant SEQ ID NO:27 at nucleotide positions 97-130. Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to make and use the recited oligonucleotides in the claimed method.

16. Claim 16 is free of the prior art, but is rejected for other reasons. No claims are allowable. This claim requires the use of a combination of primers comprising either SEQ ID NO:11 or 22, and either SEQ ID NO:12 or 20. The use of this combination of primers is not taught or suggested in the prior art.

17. Reddy et al. (WO 02/08410) is made of record as a reference of interest. On page 141, Reddy et al. disclose Sequence 237, a 336-nucleotide nucleic acid which contains the sequence of instant SEQ ID NO:28 at nucleotide positions 319-335.

18. Poutanen et al., published 31 March 2003, is made of record as a reference of interest. This reference teaches a 19-nucleotide nucleic acid primer which contains the sequence of instant SEQ ID NO:28 at nucleotide positions 2-18 (see page 2002, column 1, third line from bottom).

19. Crooke et al. (US 7,339,051), Briese et al. (US 2004/0265796), Linnen et al. (US 2006/0134609), and Peiris et al. (US 7,375,202) are also made of record as references of interest.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth R. Horlick whose telephone number is 571-272-0784. The examiner can normally be reached on Monday-Thursday 6:30AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kenneth R Horlick/
Primary Examiner, Art Unit 1637

08/21/08